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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/260,536	06/16/94	LORENCE R	57704

000757 HM12/1105
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EXAMINER	
SCHEINER,L	
ART UNIT	**PAPER NUMBER**
1648	48

DATE MAILED: 11/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/260,536	Lorence et al.
Examiner	**Art Unit**
Laurie Scheiner	1648

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 20, 1999*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *318-330* is/are pending in the applica

4a) Of the above, claim(s) *319, 321, 324-327, 329, and 330* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *318, 320, 322, 323, and 328* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 46

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

All previously pending claims have been canceled. Claims 308-320 (renumbered in accordance with Rule 126 as 318-330) are newly added. Therefore, newly presented claims 318-330 are pending. Claims 319, 321, 324, 325, 326, 327, 329 and 330 are directed to an invention that is independent from the invention originally claimed. Thus, claims 319, 321, 324, 325, 326, 327, 329 and 330 are withdrawn by the examiner based on constructive election by original presentation. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03. Please also see Paper No. 22 wherein then newly submitted claims 22, 25, 37, 39-42, 44-47, 50-63, 65, 66, 68, 70-105, 109, 110, 112-116, 118, 119, 121-124, 126, 127, 129-132, and 135-139 were withdrawn since they were directed to an invention that was independent or distinct from the invention originally claimed. Accordingly, claims 318, 320, 322, 323 and 328 (which correspond to claims 141-143, 164, 165, 167, 168, and 177 of Paper No. 25) will be examined on the merits.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "moderate" in claim 318 is a relative term which renders the claim indefinite. The term "moderate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably

apprised of the scope of the invention. Thus, other than 73-T, MK107 which is described as being "less virulent" relative to 73-T, is the sole NDV taught in the specification. Thus, it is unclear if MK107 is a less virulent velogenic strain?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 318, 320, 322, 323 and 328 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. That is, while being enabling for a method of treating...with NDV 73-T, the specification does not reasonably provide enablement for any NDV strain of moderate virulence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. That is, the specification predominantly teaches the employment of NDV 73-T strain (velogenic?) which is not sufficiently enabling for Newcastle disease viruses of moderate virulence. Moreover, moderate virulence has not been taught; MK107 is described at page 27 as being less virulent than NDV 73-T, only. One cannot determine where "moderate" falls within the continuum of virulence since the term has not been defined outside of a relative comparison with NDV 73-T. Also intravenous administration has not been taught in the specification. Again, the specification is not enabled broadly for the recitation of "moderate", nor is the term defined in the original disclosure. It appears that applicants have only disclosed one example of a particular species having less virulence with respect to NDV 73-T. Claims must be

commensurate in scope with the specification and one relative example of a control is not enabling for the use of the class or genus of NDVs having moderate virulence. In ex parte Jackson, 217 USPQ 805, even a "description of several newly discovered strains of bacteria having one particularly desirable metabolic property in terms of conventionally measured culture characteristics and number of metabolic and physiological properties does not enable one of ordinary skill in the relevant art to independently discover additional strains having same specific, desirable metabolic property." Thus, the degree of experimentation involved in locating new NDVs which would function in the claimed methods is undue in light of enablement requirement of 35 USC 112. The results achieved in instant examples are not predictive of the effect of any NDV having moderate virulence on cancers as claimed. Furthermore, examples have not been set forth which would support enablement of claims drawn to administration of any "moderate Newcastle disease viruses" to mammals.

Applicants are reminded of the legal considerations governing enablement determinations pertaining to undue experimentation as disclosed in *In re Wands,* 8 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer,* 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). Applicants are also reminded that the broad recitation of "cancer" is not enabled by the specification as originally filed. Again, it appears that fibrosarcoma would be the sole cancer type finding enablement.

The disclosure fails to meet the legal requirements dictating that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification. *In re Fisher,* 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970). *In re Vaeck,* 20 U.S.P.Q.2d 1438 (C.A.F.C. 1991). *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976). The court stated in *In re Vaeck* that "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents an undefined group of viruses, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element."

In summation, the disclosure fails to provide sufficient guidance pertaining to the molecular determinants modulating the cancer cytolytic activity of any given moderate virulence NDV, the disclosure fails to provide sufficient guidance pertaining to those variants or derivatives that can reasonably be expected to have and retain cytolytic activity. Accordingly, when all the aforementioned factors are considered together, it would clearly require undue experimentation to practice the claimed invention.

Claims 318, 320, 322, 323 and 328 are rejected under 35 U.S.C. 112, first paragraph, as being drawn to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen,* 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim,* 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A.

1976). Treatment of cancer in a mammal by administering a moderate virulence NDV is contemplated. Additional limitations are provided concerning dosage and intravenous administration. The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventor(s) had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *In re Wilder, et al.,* 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Werthheim, et al.,* 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Driscoll,* 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga,* 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988). *University of California v. Eli Lilly,* 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,* 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). *Fiers v. Sugano,* 25 U.S.P.Q.2d 1601-1607 (C.A.F.C. 1993). *In re Bell,* 26 U.S.P.Q.2d 1529-1532 (C.A.F.C. 1993). *In re Deuel,* 34 U.S.P.Q.2d 1210-1216 (C.A.F.C. 1995).

Applicants' disclosure fails to provide adequate written support for the invention as broadly claimed. That is, applicants' claims encompass a method employing any NDV of moderate virulence. However, the disclosure predominantly provides discussions and examples of NDV 73-T (a velogenic strain?), rather than a strain having moderate virulence. Again, moderate has not been defined in the specification since the focus of the specification as originally filed is not directed to strains having moderate virulence. As such, limiting the scope of the claims commensurate with that which has been described would be acceptable. Thus, a method of treating fibrosarcoma (HT 1080) in a mammal by administering NDV-M intralesionally

in an amount of 1.0 X 10^8 PFU would be commensurate with the original scope of enablement as filed. It is further noted that the specification fails to teach the dosages set forth by claim 323. Again, the disclosure fails to provide an adequate written description for subject matter encompassing NDVs having moderate virulence which would function similarly to MK107 with respect to cancer (fibrosarcoma) treatment.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 318, 320, 322, 323 and 328 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lorence et al. (1988).

Claims 318, 320, 322, 323 and 328 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Reichard et al. (1992).

Claims 318, 320, 322, 323 and 328 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Reichard et al. (1992). 2 ?

Applicant's arguments filed August 20, 1999 have been fully considered but they are not persuasive. That is, applicants' argument that examples set forth in pending application Serial No. 09/292,376 provide enablement for that which is instantly claimed is unpersuasive since enablement must be at the time of the invention.

Applicants point to Example 2 for support of various modes of administration. However, Example 2 employs strain 73-T (not a moderate virus).

With respect to the art rejections under 35 USC 102, applicants argue that the respective references fail to teach the use of a strain of moderate virulence.

The examiner argues the references cumulatively by contending that applicants' disclosure fails to define moderate virulence. That MK107 is moderate with respect to 73-T does not necessarily preclude strain 73-T from being of moderate virulence with respect to another more virulent NDV strain.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

Laurie Scheiner/LAS
October 20, 2001

LAURIE SCHEINER
PRIMARY EXAMINER